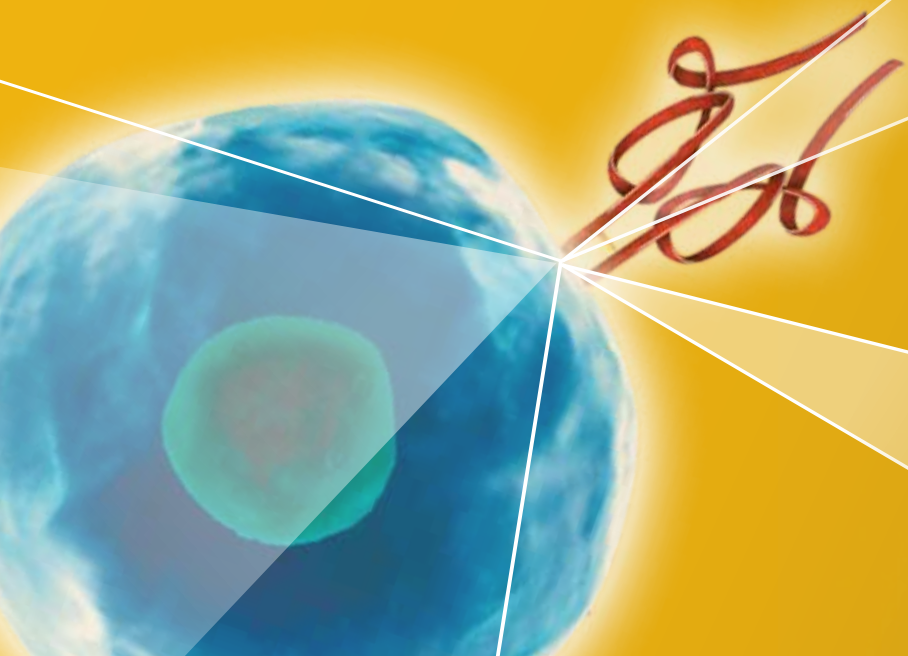
Medtronic

Do you have enough bone for dental implant placement?
Do you know what your bone graft options are?

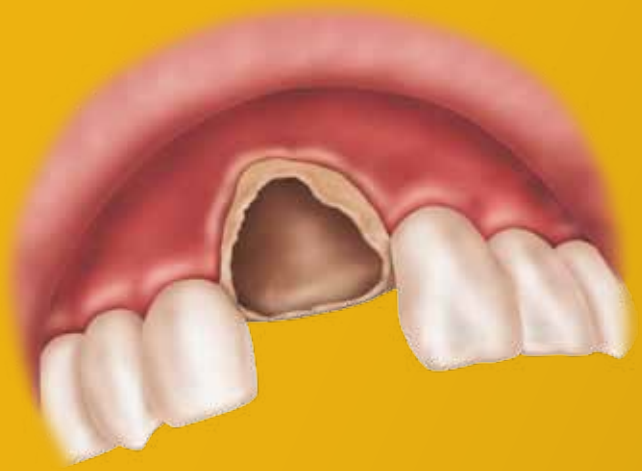
Have you considered

INFUSE® Bone Graft?



What is bone grafting?

A procedure performed to replace bone lost in the jaw that anchors teeth using one or more different bone grafting options.



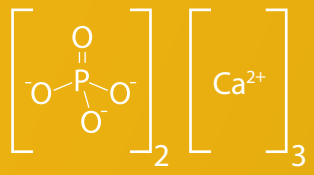
What are the different types of bone grafts?

Xenograft

Bone taken from an animal source and transplanted into your body

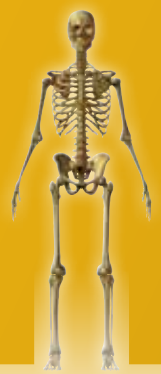
Alloplast

Synthetically made material to be used in your body as a bone graft alternative



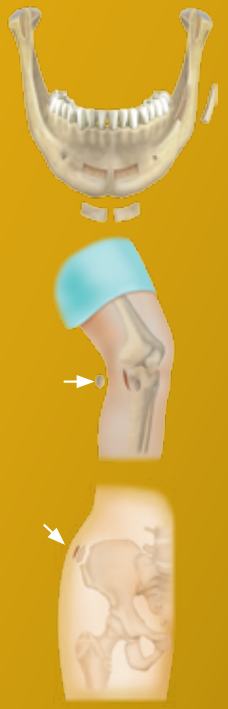
Allograft

Bone taken from a human cadaver and transplanted into your body



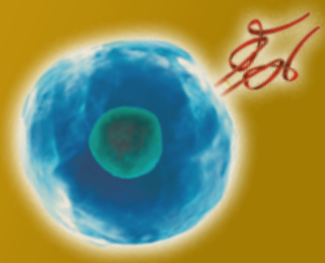
Autograft

Bone taken surgically from one part of your body and transplanted to another part



rhBMP-2

A synthetic version of a protein found naturally in your body which regulates bone healing and growth. Consists of two parts: rhBMP-2 (recombinant human bone morphogenetic protein-2) and an absorbable collagen sponge



What are the benefits and drawbacks of each graft type?

Xenograft

Benefits:

- Commonly used in surgery
- Not human derived
- Readily available
- Well documented success
- May heal small defects by itself
- Portions of the graft may turn into your own bone

Drawbacks:

- Low risk for disease transmission
- Does not stimulate your body's cells to form bone
- Portions of the graft may remain in your body for years to come
- Limited in it's ability to heal large defects by itself

Alloplast

Benefits:

- Commonly used in surgery
- Not human derived
- Readily available
- Well documented success
- May heal small defects by itself
- Portions of the graft may turn into your own bone
- No risk for disease transmission

Drawbacks:

- Does not stimulate your body's cells to form bone
- Portions of the graft may remain in your body for years to come
- Limited in it's ability to heal large defects by itself

Allograft

Benefits:

- Commonly used in surgery
- Well documented success
- May heal small defects by itself
- Portions of the graft may turn into your own bone

Drawbacks:

- Low risk for disease transmission
- Does not stimulate your body's cells to form bone
- Portions of the graft may remain in your body for years to come
- Limited in it's ability to heal large defects by itself

Autograft

Benefits:

- No potential for immune reaction or disease transmission
- Commonly used in surgery
- Well documented success
- May heal large or small defects by itself
- Portions of the graft turn into your own bone
- Transplanting your own bone forming cells to help heal the defect

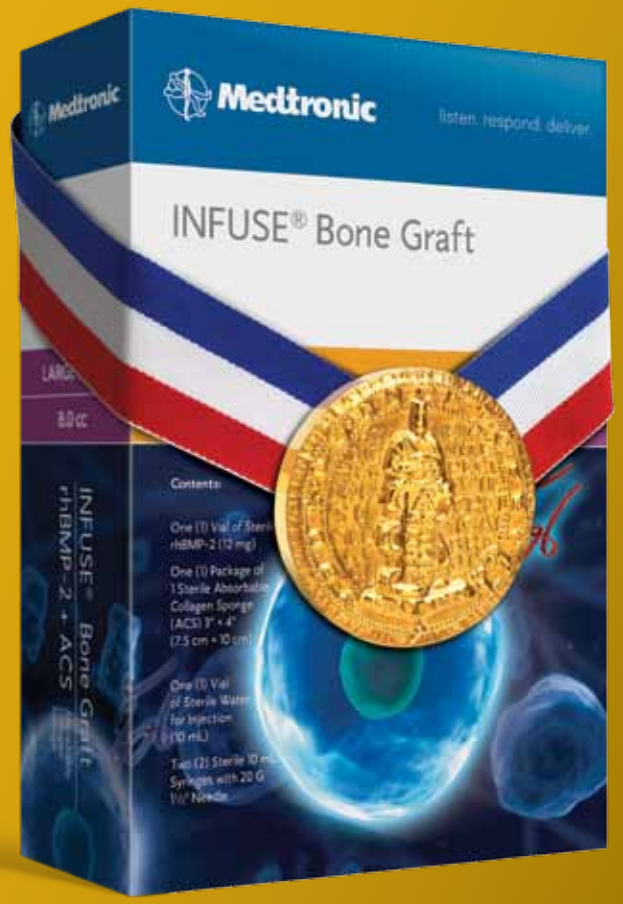
Drawbacks:

- Risk of pain and/or infection at harvest site which may last for a long time
- Additional surgery and anesthesia are required
- May not be an option for some patients

What is INFUSE® Bone Graft?

Consists of 2 parts:

- A protein which tells your body to make your own bone
- A collagen sponge used to deliver the protein to the defect site



Has been used in many different areas of the body including:

- Spine (since 2002)*
- Tibia (since 2004)*
- and Dental (since 2007)*

Winner of the 2008 Prix Galien USA Award for Best Biotechonology Agent**

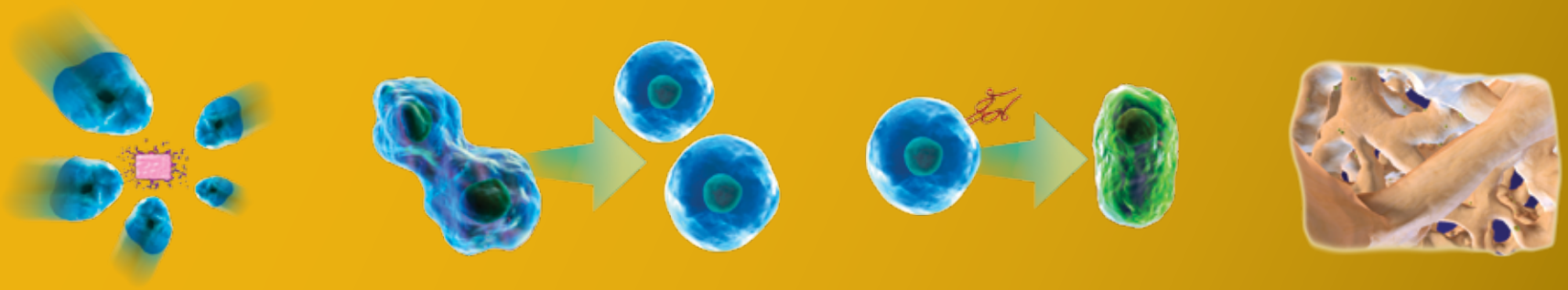
- Heralded as the "Nobel Prize" for medical research and development.
- Voting committee includes 7 Nobel laureates.

* For complete indications and more information, please see brief summary in the back of this brochure.
** To learn more about the Prix Galien USA Award visit http://www.prix-galien-usa.com/

MICHELSON TECHNOLOGY AT WORK

How does INFUSE® Bone Graft work?

1. INFUSE® Bone Graft is surgically placed where you need bone to grow.
2. A protein signal is sent out to the body to recruit cells to that area.
3. Those cells are changed into bone building cells.
4. Bone building cells begin making your own bone in that area.



Attraction | Reproduction | Differentiation | Bone

INFUSE® Bone Graft tells your body to make it's own bone!!!

What are the benefits of INFUSE® Bone Graft?

- You don't have to have a second surgery to harvest bone from another place in your body.
- Bone grows where INFUSE® Bone Graft is placed.
- Proven, predictable bone growth results.
- INFUSE® Bone Graft grows your own bone! There is no residual graft material after bone is formed.
- Proven clinically safe and effective for bone formation!

What are the drawbacks of INFUSE® Bone Graft?

- You may experience short term mild to severe facial swelling (edema) after the surgery.
- It has not been studied for use in patients under 18 years of age.
- It cannot be used in patients with an active infection at the defect site.
- It should not be used in pregnant women, women who plan to become pregnant in the next 12 months, or women who are nursing.
- It should not be used in people with immune deficiencies, due to other treatments, such as radiation therapy, chemotherapy, or steroid therapy.

Questions to Ask Your Doctor

- Why do I need a bone graft?
- Please describe the procedure to me.
- What are my bone graft choices?
- How long will my treatment take?
- What, if any, medications will be prescribed?
- What is the best treatment course for me?
- Am I a candidate for INFUSE® Bone Graft?

Vivian R.
Sinus Augmentation patient who was treated with INFUSE® Bone Graft.

Resources for Patients

www.aaoms.org
The official Web site of the American Association of Oral and Maxillofacial Surgeons. Here you will gain a better understanding of the many ways these surgical specialists can aid your oral and overall health.

www.perio.org
The official Web site for periodontists specializing in the prevention, diagnosis, and treatment of periodontal diseases and in the placement of dental implants.

www.infusebonegraft.com
This Web site contains product information, including clinical research, news, and articles about bone morphogenetic proteins, your oral health, and patient stories.

Brief Summary

BRIEF SUMMARY OF INDICATIONS, CONTRAINDICATIONS, WARNINGS, AND PRECAUTION FOR INFUSE® BONE GRAFT FOR CERTAIN ORAL MAXILLOFACIAL AND DENTAL REGENERATIVE USES

INFUSE® Bone Graft is indicated as an alternative to autogenous bone graft for sinus augmentations, and for localized alveolar ridge augmentations for defects associated with extraction sockets.

The INFUSE® Bone Graft consists of two components – recombinant human Bone Morphogenetic Protein-2 (rhBMP-2) placed on an absorbable collagen sponge (ACS). **These components must be used as a system for the prescribed indication. The bone morphogenetic protein solution component must not be used without the carrier/scaffold component or with a carrier/scaffold component different from the one described in the package insert.**

INFUSE® Bone Graft is contraindicated for patients with a known hypersensitivity to recombinant human Bone Morphogenetic Protein-2, bovine Type I collagen or to other components of the formulation and should not be used in the vicinity of a resected or extant tumor, in patients with any active malignancy or patients undergoing treatment for a malignancy, in pregnant women, or patients with an active infection at the operative site.

There are no adequate and well-controlled studies in human pregnant women. In an experimental rabbit study, rhBMP-2 has been shown to elicit antibodies that are capable of crossing the placenta. Women of child bearing potential should be warned by their surgeon of potential risk to a fetus and informed of other possible dental treatments. The safety and effectiveness of this device has not been established in nursing mothers. Women of child-bearing potential should be advised to not become pregnant for one year following treatment with this device.

INFUSE® Bone Graft has not been studied in patients who are skeletally immature (<18 years of age or no radiographic evidence of epiphyseal closure).

Please see the package insert for the complete list of indications, warnings, precautions, adverse events, clinical results, and other important medical information.

Brief Summary

BRIEF SUMMARY OF INDICATIONS, CONTRAINDICATIONS, AND WARNINGS FOR:
INFUSE® BONE GRAFT/LT-CAGE® LUMBAR TAPERED FUSION DEVICE
INFUSE® BONE GRAFT/INTER FIX™ THREADED FUSION DEVICE
INFUSE® BONE GRAFT/INTER FIX™ RP THREADED FUSION DEVICE

The INFUSE® Bone Graft/Medtronic Titanium Threaded Interbody Fusion Device is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from L2 – S1, who may also have up to Grade I spondylolisthesis or Grade 1 retrolisthesis at the involved level. The INFUSE® Bone Graft/LT-CAGE® Lumbar Tapered Fusion Device is to be implanted via an anterior open or an anterior laparoscopic approach. INFUSE® Bone Graft with either the INTER FIX™ or INTER FIX™ RP Threaded Fusion Device is to be implanted via an anterior open approach.

The INFUSE® Bone Graft/Medtronic Titanium Threaded Interbody Fusion Device consists of two components containing three parts– a metallic spinal fusion cage, a recombinant human bone morphogenetic protein and a carrier/scaffold for the bone morphogenetic protein and resulting bone. **These components must be used as a system for the prescribed indication described above. The bone morphogenetic protein solution component must not be used without the carrier/scaffold component or with a carrier/scaffold component different from the one described in this document. The INFUSE® Bone Graft component must not be used without the Medtronic Titanium Threaded Interbody Fusion Device component.**

NOTE: The INTER FIX™ Threaded Fusion Device and the INTER FIX™ RP Threaded Fusion Device may be used together to treat a spinal level. LT-CAGE® Lumbar Tapered Fusion Device implants are not to be used in conjunction with either the INTER FIX™ or INTER FIX™ RP implants to treat a spinal level.

The INFUSE® Bone Graft/Medtronic Titanium Threaded Interbody Fusion Device is contraindicated for patients with a known hypersensitivity to recombinant human Bone Morphogenetic Protein-2, bovine Type I collagen or to other components of the formulation and should not be used in the vicinity of a resected or extant tumor; in patients with any active malignancy or patients undergoing treatment for a malignancy; in patients who are skeletally immature; in pregnant women; or in patients with an active infection at the operative site or with an allergy to titanium or titanium alloy.

There are no adequate and well-controlled studies in human pregnant women. In an experimental rabbit study, rhBMP-2 has been shown to elicit antibodies that are capable of crossing the placenta. Women of child bearing potential should be warned by their surgeon of potential risk to a fetus and informed of other possible orthopedic treatments. The safety and effectiveness of this device has not been established in nursing mothers. Women of child-bearing potential should be advised to not become pregnant for one year following treatment with this device.

Please see the package insert for the complete list of indications, warnings, precautions, adverse events, clinical results, definition of DDD, and other important medical information. The package insert also matches the sizes of those sized devices that are indicated for use with the appropriate INFUSE® Bone Graft kit.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician with appropriate training or experience.

MICHELSON TECHNOLOGY AT WORK

Brief Summary

BRIEF SUMMARY OF INDICATIONS, CONTRAINDICATIONS, AND WARNINGS FOR: INFUSE® BONE GRAFT

INFUSE® Bone Graft is indicated for treating acute, open tibial shaft fractures that have been stabilized with IM nail fixation after appropriate wound management. INFUSE® Bone Graft must be applied within 14 days after the initial fracture. Prospective patients should be skeletally mature.

INFUSE® Bone Graft consists of two components – recombinant human Bone Morphogenetic Protein-2 solution and a carrier/scaffold for the bone morphogenetic protein solution and resulting bone. **These components must be used as a system. The bone morphogenetic protein solution component must not be used without the carrier/scaffold component or with a carrier/scaffold component different from the one described in this document.**

INFUSE® Bone Graft is contraindicated for patients with a known hypersensitivity to recombinant human Bone Morphogenetic Protein-2, bovine Type I collagen or to other components of the formulation and should not be used in the vicinity of a resected or extant tumor, in patients with an active malignancy or patients undergoing treatment for a malignancy. INFUSE® Bone Graft should also not be used in patients who are skeletally immature, in patients with an inadequate neurovascular status, in patients with compartment syndrome of the affected limb, in pregnant women, or in patients with an active infection at the operative site.

There are no adequate and well controlled studies in human pregnant women. In an experimental rabbit study, rhBMP-2 has been shown to elicit antibodies that are capable of crossing the placenta. Women of child bearing potential should be warned by their surgeon of potential risk to a fetus and informed of other possible orthopedic treatments. The safety and effectiveness of this device has not been established in nursing mothers. Women of child-bearing potential should be advised to not become pregnant for one year following treatment with this device.

Please see the package insert for the complete list of indications, warnings, precautions, adverse events, clinical results, and other important medical information.

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